

Application # 10/054,022  
RCE Preliminary Amendment dated March 5, 2004  
Reply to Final Office Action dated January 21, 2004

**PATENT**  
**P-4523/15**

## COMMENTS

### Introduction

Applicants have not amended the claims.

### Objections to Drawings

The Examiner objected to the drawings because they failed to show the cap recited in claim 1.

Applicants have included a replacement sheet that shows the invention as described in specification in paragraph 0008 and shown in Figure 2, and an annotated sheet indicating the changes to the original Figure 2.

### Claim Rejections

A. Claim 2 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Examiner asserts that the claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with it is most nearly connected, to make and/or use the invention.

The rejection is respectfully traversed.

Claim 2 recites the needle assembly of Claim 1, wherein the resiliently deflectable finger comprises a proximal face dimensioned for engaging the outer tube at the distal end of the hub when the shield is in the distal position for preventing proximal movement of the shield relative to the hub. Applicants respectfully point there is a relationship of elements that stops the finger's proximal face against the outer tube distal end after the spring is released. This relationship is exemplified in applicant's specification page 5 lines 5-7, which states "On the other hand, engagement between an inwardly directed flange at distal end 34 of hub 14 and an outwardly directed flange on shield 20 prevents complete separation of shield 20 from hub 14." Given the claim language and the description in applicant's specification a person of ordinary skill in the art would have no trouble in making and using the claimed invention.

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B. Claims 1, 2 and 4-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,591,138 to Vaillancourt ("Vaillancourt") in view of U.S. Patent No. 6,322,540 to Grabis et al. ("Grabis") and of U.S. Patent No. 5,779,679 to Shaw ("Shaw").

C. Claim 3 was rejected under § 103(a) as being unpatentable over Vaillancourt and Grabis as applied to claim 1 above, and further in view of U.S. Patent No. 5,779,679 to Shaw ("Shaw").

The rejections are respectfully traversed.

As amended, claim 1 recites a needle assembly having, among other things, a hub having an inner tube and an outer tube connected to each other, arranged such that a cylindrical space is defined between them, with a cannula connected to the inner tube. A shield is telescoped in the cylindrical space, the shield having a deflectable finger with an actuator engaging and projecting through a retaining aperture in the outer tube. A spring is disposed between the shield and the hub for urging the shield to a distal position, upon displacement of the actuator from the retaining aperture. In an initial state of the needle assembly, the cannula is at least partially exposed, the shield is located in a proximal position that allows such exposure, and the cannula has a safety cap disposed over at least a portion thereof.

The cited references do not render amended claim 1 obvious.

First, there would have been no motivation to combine the references in the manner asserted by the Examiner. Vaillancourt and Grabis have different and conflicting techniques for shielding a needle. Specifically, Vaillancourt begins with its shield extending over the needle, whereas Grabis begins with an exposed needle. Vaillancourt requires a twisting technique to operate the device, whereas Grabis is a push technique, which (as explicitly stated in the specification of Grabis column 3, line 29) "cannot be rotated or twisted during the retraction mode." Vaillancourt has inner and outer tubes with a shield located between, whereas Grabis has an inner tube with a shield located around that tube, i.e., there are only 2 concentric components. In Vaillancourt, the

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actuator is an integral part of the shield (see Fig. 15), whereas in Grabis, the button is a separate component that is secured to the inner tube/hub. And in Vaillancourt, the activator never moves internal to the outermost tube, whereas in Grabis the activator must be pushed internal to the outermost tube for activation.

For these reasons, applicants submit that one seeking to improve Vaillancourt would not look to Grabis. There is no suggestion in either to combine them, and in fact it is not clear how one would even do so and still retain an operative device. In addition, Vaillancourt itself discloses a solution if a user desired more or better control, which is the solution of Fig. 15. The combination is therefore not supported by either reference.

Second, even the asserted combination of the references would not have led one skilled in the art to the claimed invention. If one incorporated the button of Grabis into Vaillancourt, as asserted by the Examiner, the result would not disclose or suggest the claimed invention. For example, the overall goal of Vaillancourt is to begin with a shielded device temporarily locked in place, allow the user to un-shield the needle for use – again temporarily locked in place, and then allow the user to controllably re-shield. The device resulting from a combination would therefore begin in the shielded configuration disclosed by Vaillancourt, would allow a temporary locking in that shielded configuration, would allow a user to retract and temporarily lock the shield, and would allow a user to then release the shield to re-cover the needle.

Such a device does not read on the claimed invention, in particular the recitations of the initial state being one where the needle is exposed, and of the presence of a safety cap over the exposed needle in this initial state. Moreover, use of an initially exposed needle and safety cap goes against the overall goal of Vaillancourt. Thus, to reach the present invention, one skilled in the art would have to abandon the goal and purpose of Vaillancourt. But there is no motivation to do so. And modification of a reference in a manner that destroys its function cannot support an obviousness rejection.

For this reason, even a combination of the references would not lead to the invention of amended claim 1.

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As for Shaw, it does not provide any disclosure that would otherwise motivate one to completely ignore the goal and purpose of Vaillancourt. As its activation mechanism is very different from a push button, it is properly relied upon only for the concept that wingsets can be designed with safety features and uses a safety cap.

For these reasons, applicants submit that the cited references do not render claim 1 obvious.

In view of the remarks above, applicants respectfully request reconsideration of the application, and allowance of all claims.

If there are any additional fees related to this Amendment, such fees should be charged to Deposit Account No. 02-1666.

Respectfully submitted,

By: M. Lindsey  
Mark Lindsey,  
Agent for Applicant(s)  
Reg. No. 52,515  
201-847-6262

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Becton, Dickinson & Company  
1 Becton Drive, MC 089  
Franklin Lakes, New Jersey 07417-1880  
Doc#75462